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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,538	02/03/2005	Kenji Sunagawa	KUP-6	7543

20808 7590 01/21/2009

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
01/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,538	SUNAGAWA, KENJI	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18* is/are pending in the application.

4a) Of the above claim(s) *14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20081219*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The final clause of the claims recite that the anode and cathode "contact the electrolyte solution." As the electrolyte solution is *in vivo* human blood or fluid, this limitation inferentially includes part of a living human into the claimed subject matter. It is suggested to recite an anode and cathode “adapted to” contact the electrolyte solution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of "anode" and "cathode" are unclear in the claim language because the terms are used to describe both the sub-system component (i.e., the actual anode material) and the gross electrode system (i.e., the combination of actual anode and the immobile layer that coats the anode). For example, the final clause of the amended claims is vague because the claim language does not specify whether the electrolyte must contact the anode material, or the

immobile layer of the electrode system. The examiner is interpreting the claim to recite the latter, due to the limitations drawn to preventing oxygen and reactive substance contact, but should be amended to clarify.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor et al. (US 3,943,936, hereinafter “Rasor”) in view of Heller (US 6,294,281, hereinafter "Heller").

6. In regards to claim 10, Rasor discloses the essential features of the claimed invention, including a pacemaker capable of implantation with the tip of a catheter and requiring no chest incision (Figs. 5A-5C and 9) having a control unit (30), a heart stimulating means (output of 30), an electrocardiograph information detecting means (“trigger input” and col. 11, lines 8-13), and a fuel cell power unit (col. 3, lines 19-21), wherein the control unit outputs the control signal based on the ECG information (col. 11, lines 8-13). Further, Rasor discloses that the control unit comprises a stimulation timing determining means (“pulse forming circuit”) that decides the timing of pulses and a stimulation timing changing means (col. 11, lines 15-18) that changes the timing of stimulation when certain conditions are met. Rasor does not disclose that the fuel cell is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels

comprising an anode and cathode; wherein the anode is coated with immobile layer of mediators and oxidative enzymes for biological fuels, wherein the layer prevents oxygen existing in a biological body from contacting the anode, and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions; wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid; and wherein the anode and cathode contact the electrolyte solution. Heller teaches a biological fuel cell for use with implantable devices (col. 2, lines 60-67) that extracts electrons from oxidative reactions of biological fuels comprising an anode and cathode; wherein the anode is coated with immobile layer of mediators (redox polymer layer; cols. 5-9) and oxidative enzymes for biological fuels (cols. 9-12), wherein the layer prevents oxygen existing in a biological body from contacting the anode (col. 8, line 16; “poly(acrylic) acid”), and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions (col. 13, lines 21-47 and col. 14, lines 4-18); wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid (col. 14, lines 35-43); and wherein the anode and cathode contact the electrolyte solution (col. 14, lines 35-43) to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rasor’s invention by providing a biological fuel cell for use with implantable devices that extracts

electrons from oxidative reactions of biological fuels comprising an anode and cathode; wherein the anode is coated with immobile layer of mediators and oxidative enzymes for biological fuels, wherein the layer prevents oxygen existing in a biological body from contacting the anode, and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions; wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid; and wherein the anode and cathode contact the electrolyte solution to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries. Please note that Heller's coating material (poly(acrylic) acid) inherently prevents oxygen existing in a biological body from contacting the anode. *See* Reichert et al. (US 5,270,128; col. 3, lines 40-65) as evidence of inherency. In the alternative, it is notorious in the fuel cell arts to prevent oxygen from contacting anodes to provide the predictable result of avoiding degradation of the anode material. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Rasor's invention by preventing oxygen from contacting the anode to provide the predictable result of avoiding degradation of the anode material.

7. In regards to claims 11-13, Rasor's modified invention discloses the essential features of the claimed invention except for a transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit. It is well known in the art to provide implantable pacemakers, such as the

one taught by Rasor with transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit to provide the predictable results of modifying device function with changing patient conditions and acquiring patient diagnostic information from inside the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Rasor's invention by providing transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit to provide the predictable results of modifying device function with changing patient conditions and acquiring patient diagnostic information from inside the body.

Response to Arguments

8. Applicant's arguments filed 10/31/2008 have been fully considered but they are not persuasive. Applicant argued that Heller teaches away from contacting blood or body fluid because of various materials that are disclosed as usable with the system, but not biocompatible. However, it is respectfully asserted that this does not obviate the fact that Heller's invention was designed for, and explicitly disclosed as usable in contact with the blood or other body fluids (col. 14, lines 35-43) within the scope of the claim language.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762